



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,205	08/08/2003	Terrence S. McGrath	6619-85-1CON	4081
30448 7590 01/12/2007 AKERMAN SENTERFITT P.O. BOX 3188 WEST PALM BEACH, FL 33402-3188			EXAMINER EBRAHIM, NABILA G	
			ART UNIT	PAPER NUMBER
			1618	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/637,205	MCGRATH ET AL.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,10,11 and 13-21 is/are pending in the application.
- 4a) Of the above claim(s) 20 & 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,10,11 and 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 20, and 21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Applicant's remarks and amendments to the claims dated 10/25/06 is acknowledged.

Status of Claims

Claims 1, 2, 4-7, 10, 11, and 13-21 are pending in the application.

Claims 3, 8, 9, 12 were cancelled.

Claims are 1, 2, 4-7, 10, 11, and 13-19 under current examination.

Status of Office Action: Non-Final

Any rejections that were not reiterated in this office action are herein withdrawn.

Election/Restrictions

1. Newly submitted claims 20, and 21 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims have a different invention because it is not applied to skin and mucous membrane and further it does not increase the subepithelial partial oxygen pressure.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20, and 21 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1618

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 10 recites the limitation "the level of oxygen" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 6, 13, 20, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. US 5,766,490 (hereinafter Taylor).

Taylor teaches a process to enable the production of water highly enriched with oxygen with a higher concentration of dissolved solved oxygen and with longer retention of the dissolved oxygen in the water (col. 2, lines 41+). The superoxygenated water of Taylor can be advantageously employed in, for example, increasing the oxygen content of blood and tissues; oxygenation of wounds to increase the rate of healing and to reduce infections; oxygenated organ transplant storage media; tumor oxygenation for radiation therapy and chemotherapy; lung bypass by oxygenated liquids in case of pulmonary deficiencies; carbon monoxide poisoning; mouthwashes, dentrifices; topical, including cosmetic, treatment media; contact lens treating solutions; and cell level therapeutic applications (col. 5, lines 26+). Taylor discloses that oxygen is distributed in the water as bubbles and also as some amount of oxygen dissolved in the water (col. 7, lines 18+). Claim 1 recites the limitation " for a time sufficient to

Art Unit: 1618

increase the subepithelial partial oxygen pressure from about 30% to about 12)% above baseline pO_2 ". The time is considered inherent since the application is the same way "topical" and applied to the same lesions "wounds" and for the same reason which is enhancing healing and because the pharmaceutical vehicle comprising the oxygen would inherently be left on the lesion for a suitable time that will give oxygen bubbles the chance to work sufficiently on the tissue.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a). Claims 1, 2, 4-7, 10, 11, and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. US 5,766,490 in view of Ladin et al US 5, 792, 090 (hereinafter Ladin) and further in view of Kolta et al US 6, 139, 876 (hereinafter Kolta).

Taylor has been discussed above.

Taylor does not specifically disclose the oxygen bubble size.

Ladin discloses a method of healing of surface wounds, including burns, which is facilitated by increasing the wound oxygen tension through the application of an oxygen-generating wound dressing which renewably and non-sustainingly chemically generates oxygen. The wound dressing contains an oxygen permeable membrane and an oxygen supply solution. Because the oxygen chemically produced by the subject invention may include both gaseous oxygen as well as dissolved oxygen, the membrane pore sizes of from 0.01 to 10 micron, preferably 0.1 to 1.0 microns are preferred to limit the oxygen passage (col. 5, lines 16+).

The two references did not disclose a method to treat anaerobic bacterial infections.

Kolta discloses a gelatin with increased oxygen content for pharmaceutical, cosmetic and/or veterinary use. The gelatin comprises a gelling agent and a solvent, furthermore oxygen in a substantially even distribution with a pressure exceeding normal atmospheric pressure (abstract). Kolta teaches that gelatin and the oxygen encapsulated therein will have special synergetic effects. The intensive presence of oxygen will prevent proliferation of anaerobe bacteria which otherwise would rapidly multiply in the gelatin (col. 2 line 12+)

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to expand the teaching of Taylor by realizing a fine size of the oxygen bubbles because the size of the bubble relate inversely with the penetration of the tissue and also to ensure the effect of the method on the anaerobic bacteria because Kolta discloses that the presence of oxygen ensures the prevention of proliferation of anaerobic bacteria. The expected result would be a method for increasing skin oxygenation by applying a composition of high oxygen concentration to a wound, or burn in a topical application or a bath.

Response to Arguments

4. Applicant's arguments filed 10/25/06 have been fully considered but they are not persuasive.

In view of the new rejection, the arguments related to (White) US 4,366,169 is considered moot and will not be discussed.

a. Applicant respectfully disagrees with the interpretation of the section (col. 5, lines 16+), which discloses the use of the membranes. These membranes are to prevent transport of solid catalyst and dissolved salts, and to isolate pathogens greater than 0.45 microns, which is a restriction based on a non-deformable particle size. Membranes of the type disclosed in Ladin will not stop any gas from being transported through the membrane from a high pressure side to a low pressure side, nor will it define a size of a bubble of a gas as it will not inherently provide a sheering force at the exit of the pore to break a large bubble into a small bubble. As with all membranes, any non-absorbed liquids and gases can deform to the shape of the pore and pass through the pore as illustrated below for a single large gas bubble encountering a single pore of a membrane. Therefore, the pore size cannot define the diameter of the bubble. **To respond** to this argument, the reference (Ladin) teaches an oxygen permeable membrane, made of cross-linked hydrogel preferable, hydrophobic microporous membranes (col. 4, lines 55+ bridging to col. 5, lines 1+). Regarding the interpretation of the Applicant of non-absorbed liquids and gases can deform to the shape of the pore and pass from the higher pressure to the lower pressure, it is not clear in the sense that the reference does not disclose any pressure exerted in any direction to help the gaseous oxygen to pass through the membrane. Accordingly, it is the position of the Examiner that the pore size will define the oxygen bubble

Art Unit: 1618

size while preventing bigger size pathogens and salts from passing through the membrane. Examiner would like to draw the attention of the Applicant that instant independent claim 1 does not recite the bubble size, this limitation is recited in instant claim 14,

b. Ladin does not teach or suggest that having oxygen in the form of a microbubble can be effective at increasing the subepithelial partial pressure of oxygen. Furthermore, Ladin does not demonstrate that the oxygen of their composition can pass through an epithelial layer.

To respond to this argument, this limitation is inherent since treatment of wound for enhancing healing is known in the art and applying Oxygen to a wound or burn will inherently pass through the epithelial layer and increase the subepithelial partial pressure of oxygen.

c. The wound dressing of Ladin is intended "to provide oxygen levels similar to those produced by moderate hyperbaric oxygen treatment" (col. 3 ln 17-20) where hyperbaric oxygen treatment is stated to be a treatment where "the relative oxygen concentration of the deep dermis (1.8-2.2 mm) is unchanged". Hence, Ladin teaches away from expecting a surface treatment to increase subepithelial levels of O₂ when treating skin.

To respond: Ladin is introduced to the rejection to verify the fact that the Oxygen microbubble size was known in the art the time the invention was made.

d. The bubbles that form in the gels of Kolta are not microbubbles that have micrometer or nanometer dimensions. Microbubbles would not result in the scattering of light at the boundaries of the bubbles and would not cause an opaque appearance (col. 4 ln 40 - 46) as disclosed in Kolta. The microbubbles of the present invention are described as being smaller than the bubbles released in a carbonated beverage, where a high proportion of the

Art Unit: 1618

bubbles are not visible (page 6 ln 12-18). The bubbles formed upon the release of the pressure upon exposure to air in Kolta are necessarily large and are not microbubbles.

To respond to Applicant's argument: Kolta is introduced to the rejection to show that treatment of anaerobic bacteria by a high oxygen bubble composition was known in the art at the time the instant invention was made.

e. Furthermore, Kolta teaches away from oxygen alone being able to heal tissue, stating, "We have supposed that during The absorption of proloxin the oxygen supply alone does not support the process of crating new tissues to a sufficient extent" (col. 14 ln 1-3). This synergistic effect cannot be present in the superoxygenated composition of the present invention because it lacks the gelatin. Therefore, the composition of Kolta that teaches a synergistic effect without microbubbles can not obviate or " motivate a superoxygenated composition which lacks the important synergistic component when Kolta teaches that oxygen alone is insufficient to promote healing.

To respond: Even if Kolta believes that oxygen cannot solely improve healing, the composition having oxygen would inherently achieve the same effects, note that the language of the instant claim 1 includes the words "comprising" which permits further steps in the method recited and also includes the phrase "consisting essentially of", it is noted that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. If the applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of" applicant has the burden of showing that the introduction of additional steps or

Art Unit: 1618

components would materially change the characteristics of applicant's invention.

Accordingly, since applicant claims a superoxygenated composition of oxygen microbubbles consisting essentially of oxygen in a pharmaceutically acceptable vehicle, it is the Applicant's burden to show that the composition does not include any further materials that changes the viscosity of the composition or turns it into a gel form and/or the pharmaceutically acceptable vehicle is not an ingredient that turns the composition into a gel form.

f. Kolta does not disclose that the oxygen in the gel attacks anaerobe bacteria infections present in the wound, only that it will prevent their proliferation in the gel.

To respond: The instant claims do not recite the mechanism of action of oxygen in case of bacterial infection, claims do not recite if oxygen in the instant case work as bacteriostatic or bactericidal. In addition claim 1 recites merely "a method of increasing tissue oxygenation", no treatment, no improving, not even promoting healing.

Correspondence

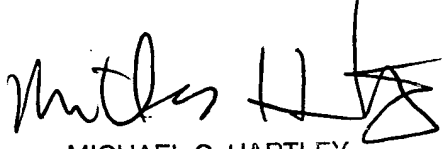
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim, M.D
1/7/07


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER